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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,663	10/05/2001	Francis Blanche	03806.0517	2019

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

12

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,663

Applicant(s)

BLANCHE ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-26 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18, 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Final Rejection

Claims 10-26 are pending.

Applicant's traversal, the Declaration filed under 1.131, the addition of claims 24-26 in paper no. 10 filed in 4/2/03 is acknowledged and considered.

It was not apparent to the examiner if claims 12 and 13 were supposed to be amended in paper no. 10 filed on 4/2/03 because a statement to amend claims 12 and 13 was set forth on page 2 of the amendment. An amendment to claims 12 and 13 was not submitted with the Applicant's response. The examiner contacted the applicant's representative, Charles Nieblyski on 4/10/03 to determine if claims 12 and 13 were supposed to be amended. Mr. Nieblyski indicated to disregard the statement to amend claims 12 and 13. Thus, the amendment to claims 10 and 21 in paper no. 10 filed in 4/2/02 is acknowledged and considered.

Election/Restriction

This application contains claims 19 and 20 drawn to an invention nonelected with traverse in Paper No. 7 filed on 7/17/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 4/9/1999. It is noted, however, that applicant has not filed a certified copy of the application 99/04443 as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1635

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22, and 23 remain and claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 2002/0031527, effective filing date 11/16/98) taken with (Sene et al. US Patent No. 6,451,256). Wu teaches a method for the preparation of a long-term storage stable adenovirus liquid formulation, comprising the steps of provides an adenovirus and combining said adenovirus with a solution comprising a buffer and a polyol (glycerol), whereby said adenovirus liquid formulation retains high infectivity (page 29). The buffer used for preparing the freeze-dried adenovirus formulation is Tri-HCl (page 3). Wu teaches that the formulation can be stored at 4°C (abstract). Wu further teaches a method for the preparation of a long-term, storage stable adenovirus formulation, comprising the steps of providing adenovirus with a solution comprising a buffer, a bulking agent, a cryoprotectant and a lyoprotectant; and lyophilizing the solution, whereby lyophilization of the solution produces a freeze-dried cake of the adenovirus formulations that retains high infectivity and low residual moisture (page 2). The list of bulking agents, cryoprotectant and lyoprotectant are on pages 2-3. The composition for preserving adenoviral particles taught by Wu does not have added divalent metal cations or alkali metal cations. Buffering agents and other types of pH control can also be added simultaneously in order to provide for maximum buffering capacity for the adenovirus formulation. Thus, buffering agents are particularly important for virus preparations that aggregate or denature at sub-optimal pH ranges. However, Wu does not specifically teach a composition comprising adenovirus particles and a buffer solution that maintains the pH of said composition between 8.0 and 9.6 and glycerol.

Art Unit: 1635

However, at the time the invention was made, Sene teaches that a Tris buffer solution for preserving recombinant virus particles in frozen or liquid form (abstract). Sene teaches that the infectious viruses gain stability when the aqueous solution used has a basic pH between 8 and 9, preferably 8.5 (column 3). The pH of the buffer is about 8 to 9, preferably 8.5 (column 3-4 and 6-12).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the work of Wu taken with Sene to produce a composition comprising adenovirus particles, glycerol, and a buffer with a pH of 8-9. One of ordinary skill in the art would have been motivated to use the buffer at in the specific pH range taught by Sene because of the gain in stability of the viruses when the solution used has a basic pH.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive.

The Declaration under 1.131 filed on 4/2/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the 103(a) reference. There are two inventors (Francis Blanche and Shian-Jiun Shih) and only Francis Blanche has signed the Declaration. MPEP 715 states, "the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. Francis Blanche and Shian-Jiun Shih are

considered to be the inventor on this application. Thus, both inventors are required to sign a Declaration under 1.131.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Art Unit: 1635

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER